**Reviewer’s report**

**Title:** Makes FLASH the difference between intervention group and treatment-as-usual group in an evaluation study of a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on an intensive insulin therapy: study protocol for a randomized controlled trial

**Version:** 0  **Date:** 16 Oct 2017

**Reviewer:** Andreas Melmer

**Reviewer's report:**

Dear authors,

thank you for giving me the opportunity to review your study protocol entitled "Makes FLASH the difference? Protocol for a randomized controlled trial between intervention group and treatment-as-usual group to evaluate a structured education and treatment programme for flash glucose monitoring devices in people with diabetes on an intensive insulin therapy", which was proposed for publication in "Trials".

The present study protocol aims to evaluate the patient-education program "FLASH", which by itself is intended to impart patients with comprehensive knowledge about features offered by the Abbott Freestyle libre Flash Glucose Monitoring System (FGMS). FLASH comprises 4 education sessions à 90 minutes covering principles of FGM, understanding trend-arrows, analyzing glucose values and trends, using data to recognize glucose patterns and to adjust the therapy, and dealing with barriers. As stated in the manuscript "The FLASH program is a structured education and treatment programme taking place in a group setting of three to eight patients aged 16 to 75 years […] offering patients information and strategies needed to be able to perform a better diabetes self-management.

The study proclaims that insufficient knowledge about glucose patterns offered by FGMS and missed implementation in their actual treatment strategy may at least in part explain why HbA1c remains unaltered after using FGMS.

The protocol describes a multicenter, open-label controlled intervention study, with HbA1c as its primary endpoint, time in range and reduction of hypoglycemic events were secondary outcomes.
The proposed study aims to investigate an important aspect, as a considerable number of patients already use FGMS based devices for controlling their blood glucose. However, in its current form, there are some points that should be reconsidered:

1. The manuscript offers incomplete information about how FLASH was performed. The authors state that "FLASH uses different modern educational techniques". Please describe these techniques and also explain whether all of those techniques were used or if techniques were adapted to the patients individual capacities.

2. The manuscript offers incomplete information about how "professional employees" were educated in using the program. Who was responsible for quality control, monitoring and/or queries?

3. The authors mention that "Randomly chosen study center will be audited by the responsible FIDAM employees to proof the adherence to the study protocol". Why did the authors perform draw sampling? What was the estimated/predefined number and/or frequency of draw samplings?

4. Data were obtained from multiple participating study centers in Germany. In which way were those data collected? Where data written in CRFs or eCRFs? Who was responsible for data management? In which way were the data/CRFs/eCRFs transmitted? Is there a data safety committee, a website available for public information (as is recommended for multicenter studies), or monitoring procedures on a regular basis?

5. The authors state that "Financial grants for every patient who will fulfill the complete protocol will be agreed in a contract with every study center. This shall motivate the responsible personnel as well as the participating patients in both groups." I`m not fully aware of the legal requirements in Germany, but financial devotions should be noted as a potential study limitation.

6. In the section "inclusion criteria", the authors mention "indication for using a flash glucose monitoring system". Please describe the indication for using FGMS.

7. There is little information about the planned statistical analysis. The authors plan to conduct a plethora of questionnaires. Are all of these outcome variables continuous? In case of categorical data determined over more than 2 time points, different approaches may be required (ordinal regression analysis, Kruskal wallis, etc…). Please comment.
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